



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|--------------------------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/521,743 | 01/19/2005 | Jan Hall | 21547-00302-US1 | 1919 |
| 30678 | 7590 | 05/15/2008 | EXAMINER | |
| CONNOLLY BOVE LODGE & HUTZ LLP | | | BUMGARNER, MELBA N | |
| 1875 EYE STREET, N.W. | | | ART UNIT | PAPER NUMBER |
| SUITE 1100 | | | 3732 | |
| WASHINGTON, DC 20036 | | | MAIL DATE | |
| | | | 05/15/2008 | |
| | | | DELIVERY MODE | |
| | | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|----------------------------------|
| Office Action Summary | Application No. 10/521,743 | Applicant(s) HALL, JAN |
| | Examiner Melba Bumgarner | Art Unit 3732 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 April 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 21-30 is/are pending in the application.

4a) Of the above claim(s) 26-30 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 21-25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/0256/06)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21-25 are provisionally rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claims 18-28 of copending Application No.

10/520,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art as to the functional limitations of the implant with respect to the bone hole such as the space formed between the implant part and bone when the implant is fitted into the bone hole.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 21-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims appear to recite part of the human body in combination with the structure of the claimed invention, defining a limitation on the jaw bone hole in the phrase “said jaw bone hole is configured to receive bodily fluids via the jaw bone and GSS from said implant.” It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 USC 101. The grant of limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). Applicant needs to clearly state using inferential language that the human anatomy is not claimed. For examination purposes, the claims will be considered as if such limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (4,186,486). Gordon discloses an implant for fitting into a jaw bone hole having adjacent soft tissue 34 comprising an inner implant part 14 having an inner implant diameter, an outer implant part 22 having an outer implant diameter, and GSS (column 2 line 50) disposed on a surface of the implant, the GSS configured to be released from the implant surface and

configured to interact with bodily fluid (column 2 line 53), the implant is configured to be covered by the soft tissue (column 3 line 15). Patentable weight is not given to the intended use of the implant with respect to a jaw bone hole; however, it is noted that Gordon shows the inner implant diameter is configured to be as least as large as the inner hole diameter (figure 5), the outer implant diameter is configured to be lesser than the outer hole diameter (figures 5, 6); and the GSS is used for bone volume increase adjacent to the implant part. The GSS is disposed on surface of the implant other than the outer surface of the implant (figure 2). The implant comprises bone substitute disposed adjacent to an implant part (column 3 line 35).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Aoyagi et al. (4,146,936). Gordon discloses an implant that shows the limitations as described above; however, Gordon does not show GSS disposed as two or more layers on the outer surface of the implant. Aoyagi et al. teach an implant having GSS disposed as two or more layers on the outer surface of the implant (column 3 line 60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the GSS being disposed in layers in order to have an implant with excellent mechanical strength and affinity to body tissue in view of Aoyagi et al.

Response to Arguments

9. Applicant's arguments with respect to claims 21-25 have been considered but are moot in view of the new ground(s) of rejection. As to the double patenting rejection, Applicant argues the difference in the spatial relationship between the claimed implant and the bone to which it is to be implanted, but the claimed implants are not patentably distinct from each other.

Conclusion

10. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached at 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Melba Bumgarner/
Primary Examiner, Art Unit 3732